

Policy Memorandum No. 33
Subject: Institutional Performance Review
Departments Affected: All

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INSTITUTIONAL PERFORMANCE REVIEW

The efficient conduct and the quality of clinical trials depend on accurate and timely submission of data. The Statistics and Data Management Center (SDMC) monitors the submission of data, forms and specimens by each institution. Monthly reports on the submission of initial forms, follow-up forms, specimens and timeliness of patient follow-up are provided for each institution along with the performance statistics for their pertinent sites. Each Principal Investigator (PI) is responsible for their institution and their associated components and affiliates in meeting expectations for data and specimen submission. An institution's registration privileges may be suspended when performance is delinquent for three consecutive months in any one or more performance categories.

The four performance categories and their specifications are:

1. **Initial Forms Set (IFS):** The initial forms set is protocol specific and typically consists of the on-study form, baseline disease assessment form, baseline specimens, operative and pathology reports, baseline Quality of Life forms and radiology reports and materials if applicable. A patient registration is delinquent if any form within the IFS has not been submitted and is more than 30 days overdue. A site's performance is inadequate if IFS submission for greater than 10% of registrations within the past 13 months are delinquent, or if IFS submission for ANY registration more than 13 months ago is delinquent for this measure.
2. **Vital Status Update:** For patients still known to be alive, whether on or off treatment, and requiring follow-up per protocol, a patient's data are delinquent if the date of the patient's last contact is more than 60 days overdue. A site's performance is inadequate if greater than 15% of their patients are delinquent for this measure.
3. **Post-baseline Forms Submission:** Post-baseline forms, report or other protocol-specified document are included in this measure. A site's performance is inadequate if greater than 5% of the required materials expected in the last 13 months have not been received and are more than 60 days overdue.
4. **Specimen Submission:** This measure includes any post-baseline specimen for which an expectation has been posted. Expectations for specimens are resolved in the SWOG Specimen Tracking System by the site reporting the shipment of the specimen or reporting that the specimen cannot be collected and submitted. A specimen is delinquent if the expectation has not been resolved and is more than 30 days overdue. A site's performance is inadequate if greater than 10% of post-baseline specimen expectations that were posted within the past 13 months are delinquent or if ANY specimens expectations posted more than 13 months ago have not been resolved.

A letter of warning will be sent to the site PI after two consecutive months of delinquent performance in one or more performance categories. If performance is still inadequate at the third month, and there is no evidence of improvement, a letter of suspension of registration privileges will follow. If the information in overdue categories is based on a small denominator or under other extenuating circumstances the Group Chair, Executive Officer for Quality and Group Statistician may choose to waive the suspension at that time. When a suspension letter is sent, the institution is given until the following month's report before the suspension is activated, in order to provide time for the site to complete registrations for eligible patients who are currently engaged in the pre-registration eligibility evaluation process. If the IPR statistics are found to be within compliance at this next report, the suspension will be lifted. To lift a suspension, an institution must have all performance categories within acceptable limits, regardless of which category caused the suspension.